

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

WARSAW ORTHOPEDIC, INC.,
MEDTRONIC SOFAMOR DANEK
U.S.A., INC., MEDTRONIC PUERTO
RICO OPERATIONS CO., and
OSTEOTECH, INC.,

Plaintiffs,

v.

NUVASIVE, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No.: 12-cv-2738-CAB (MDD)

**ORDER GRANTING
COUNTERDEFENDANTS' MOTION
FOR SUMMARY JUDGMENT OF
NON-INFRINGEMENT OF U.S.
DESIGN PATENT NO. 652,922**

Before the Court is the motion for Summary Judgment of Non-Infringement of U.S. Design Patent No. 652,922¹ ("the '922 patent") brought by plaintiffs/counterdefendants,² collectively "Warsaw". [Doc. No. 207, 246 (sealed).] The motion was opposed by defendant/counterclaimant NuVasive, Inc. [Doc. No. 248 (sealed).] Warsaw filed a reply.

¹ A copy of the patent is attached as Exhibit G to the Second Amended Counterclaim. [Doc. No. 85-7.]

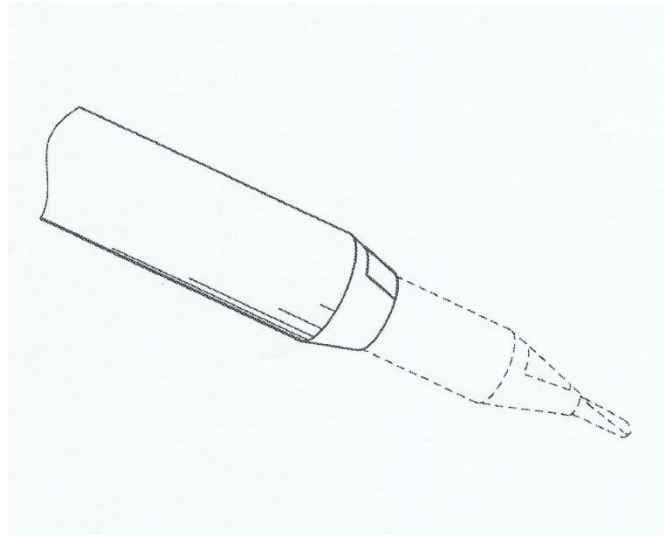
² The Plaintiffs/Counterdefendants are Warsaw Orthopedic, Inc., Medtronic Sofamor Danek U.S.A., Inc., Medtronic Puerto Rico Operations Co., Osteotech, Inc., Medtronic, Inc., Medtronic Sofamor Danek Deggendorf, GmbH, Medtronic Logistics, LLC, Medtronic Xomed, Inc., and Spinalgraft Technologies, LLC.

[Doc. No. 251 (sealed).] The Court held a hearing on the motion and, having considered the submissions of the parties and the arguments of counsel, the motion is GRANTED.

I. Background

Design patents protect new, original, and ornamental designs for an article of manufacture. 35 U.S.C. § 171; *Richardson v. Stanley Works, Inc.*, 597 F.3d 1288, 1293 (Fed. Cir. 2010) (a design patent, unlike a utility patent, limits protection to the ornamental design of the article). NuVasive is the assignee of the '922 patent for an ornamental design for a dilator. [Doc. No. 85-7, Claim.] The dilator is a tube used to gradually dilate tissue to create initial access into a patient for performing surgical procedures. NuVasive asserts that Warsaw's 16mm NIM-Eclipse Direct Lateral Dilator infringes the '922 patent.

The sole figure of the '922 patent is reproduced below:



The figure shows a perspective view of a dilator. The patent description explains that:

The broken lines illustrate part of the distal portion that forms no part of the claimed design. The dilator is circular as seen from the end. The break line is shown at the wide end to indicate that only the distal portion of the dilator is illustrated. Only one view of the article is shown in the drawing or described in the specification. It is understood that the appearance of any part of the article not shown in the drawing or described in the specification forms no part of the claimed design.

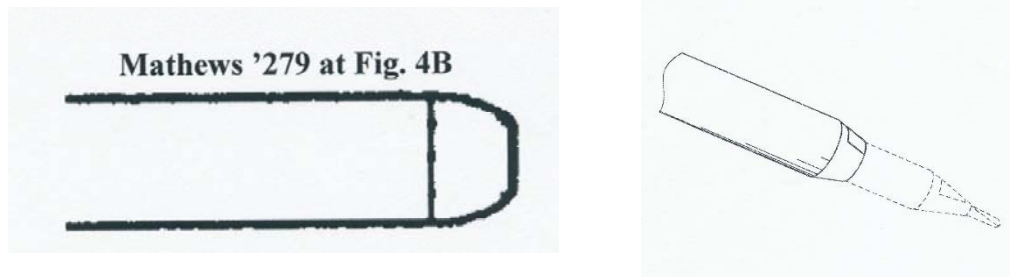
1 [Id., Description.] The figure includes a cylindrical main body, a tapered section, and a
2 rectangular surface indicium on the tapered section of the cylindrical main body at the
3 distal edge. This indicium corresponds to the edges of an electrode that allows a user to
4 detect and avoid nerves when employing the dilator in a surgical procedure. [Doc. No. 239,
5 ¶5.]

6 On October 16, 2013, Warsaw filed a petition requesting *inter partes* review of the
7 ‘922 patent, arguing the patent was invalid under 35 U.S.C. §§ 102 and 103. Warsaw
8 challenged the patentability of the ‘922 patent, in part, on the basis that its features are
9 purely functional. *See Richardson*, 597 F.3d at 1293-94 (if a patented design is primarily
10 functional rather than ornamental, the patent is invalid). “When the design also contains
11 ornamental aspects, it is entitled to a design patent whose scope is limited to those aspects
12 alone and does not extend to any functional elements of the claimed article.” *Id.* at 1294.

13 The Patent Trial and Appeal Board of the Patent and Trademark Office (“PTAB”)
14 construed the claim of the ‘922 patent to separate its functional and ornamental aspects.
15 *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1405 (Fed. Cir 1997) (where a
16 design contains both functional and non-functional elements, the scope of the claim must
17 be construed in order to identify the non-functional aspects of the design as shown in the
18 patent). The PTAB construed “the claim of the ‘922 patent to be the ornamental design of
19 a dilator, including, as seen in the figure, a Cylindrical Main Body, a Tapered Section
20 extending from the distal end of the Cylindrical Main Body, and Surface Indicia/Electrode
21 on the Tapered Section in the shape of a rectangle, with one side of the rectangle being
22 extensive with the distal edge of the Tapered Section.” [Doc. No. 174-6, at 8-9.]³

23
24
25
26
27
28 ³ Page references are to the docketed CM/ECF assigned page numbers of a document.

1 The PTAB rejected Warsaw's contention that the design was primarily functional
2 and found that the tapered section and the surface indicia/electrode are not purely
3 functional elements of the claimed design. The PTAB determined that the function of the
4 tapered section, to aid in tissue penetration of the surgical dilator, could be accomplished
5 by tapering shapes having different ornamental appearances. The Administrative Patent
6 Judge ("APJ"), by way of example, found that the "more rounded shape of tapering" used
7 in a prior art dilator tube depicted in U.S. Patent No. 5,171,279, Fig. 4B, "differs noticeably
8 from the frustoconical tapered section of the dilator claimed in the '922 patent." [Doc.
9 No. 174-6, at 7.]



16 Similarly, with regard to the nerve detection function of an electrode on the tapered
17 section of the dilator, the PTAB determined that that function could be accomplished using
18 electrodes that have substantially different shapes and orientations, and therefore
19 substantially different ornamental appearances. [*Id.*] Again by way of example, the APJ
20 compared the triangular-shaped electrode employed on NuVasive's currently available
21 dilator with the rectangular-shaped electrode of the design. [*Id.*, at 6-7.] The PTAB
22 declined to institute *inter partes* review.

23 Following the PTAB decision, the parties briefed the issue of claim construction for
24 this Court's consideration. The Court adopted the PTAB's construction for the purpose of
25 identifying the non-functional aspects of the design as shown in the patent. [Doc. No. 183,
26 Transcript of Hr'g., at 66-69.] Warsaw now moves for summary judgment of non-
27 infringement on the basis that the design features of the accused dilator and the '922 patent
28

1 are sufficiently distinct and plainly dissimilar, such that NuVasive cannot prove
2 infringement as a matter of law.

3 **II. Legal Framework**

4 Pursuant to Fed. R. Civ. P. 56(a), summary judgment is appropriate when “there is
5 no genuine issue as to any material fact and the moving party is entitled to judgment as a
6 matter of law.” Material facts are those that may affect the outcome of the case. *See*
7 *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute as to a material fact
8 is genuine if there is sufficient evidence for a reasonable jury to return a verdict for the
9 non-moving party.

10 The moving party bears the burden to show that no genuine issue of material fact
11 exists. *See Celotex Corp. v. Caltrett*, 477 U.S. 317, 323-24 (1986). If this burden is met,
12 the burden shifts to the non-moving party to set forth affirmative evidence from which a
13 jury might return a verdict in its favor. All evidence must be viewed in the light most
14 favorable to the non-moving party. At this stage, a court does not assess the credibility or
15 weigh the evidence, but simply determines whether there is a genuine factual issue for trial.
16 *Anderson*, 477 U.S. at 249.

17 A design patent is infringed “[i]f, in the eye of an ordinary observer, giving such
18 attention as a purchaser usually gives, two designs are substantially the same, if the
19 resemblance is such as to deceive such an observer, inducing him to purchase one
20 supposing it to be the other.” *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 670
21 (Fed. Cir. 2008), *citing Gorham Co. v. White*, 81 U.S. 511, 528 (1871). The patentee must
22 prove by a preponderance of the evidence that an ordinary observer, familiar with the prior
23 art designs, would be deceived into believing that the accused product is the same as the
24 patented design. *Richardson*, 597 F.3d at 1295.

25 Where the claimed and accused designs are “sufficiently distinct” and “plainly
26 dissimilar,” the patentee fails to meet its burden of proving infringement as a matter of law.
27 *Egyptian Goddess*, 543 F.3d at 678. If the claimed and accused designs are not plainly
28 dissimilar, the inquiry may benefit from comparing the claimed and accused designs with

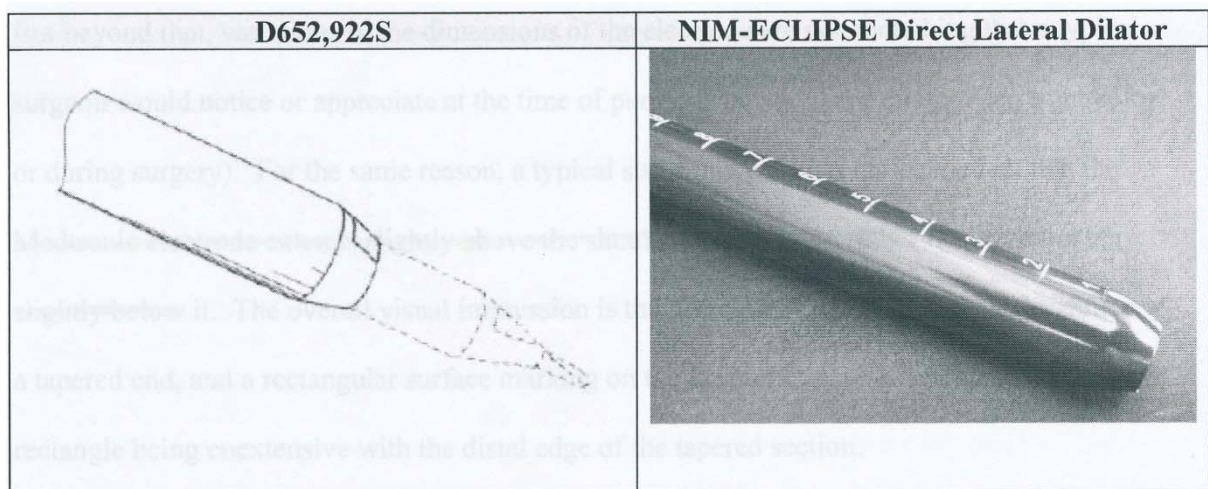
prior art to identify differences that are not noticeable in the abstract but would be significant to the hypothetical ordinary observer familiar with the prior art. *Id.*

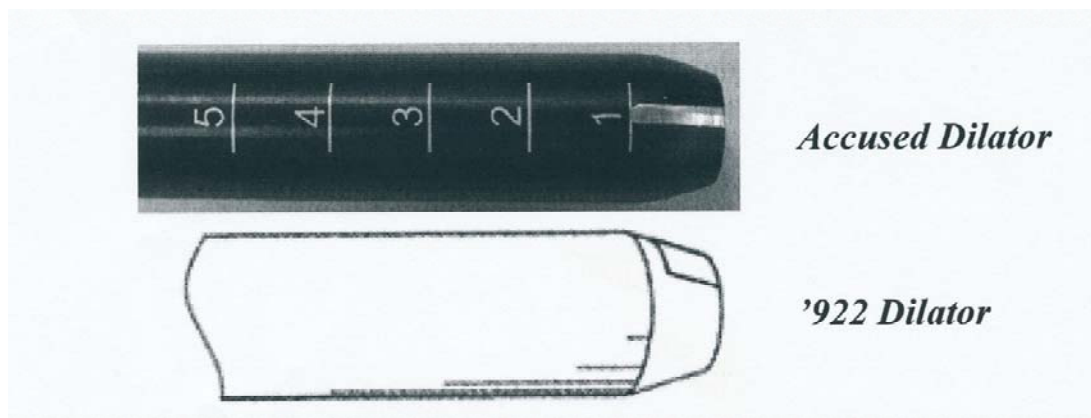
When the claimed design includes several elements, the ordinary observer test must be applied by comparing similarities in overall designs, not similarities of ornamental features in isolation. *Richardson*, 597 F.3d at 1295. Similarity at a conceptual level, however, is not sufficient to demonstrate infringement of the claimed designs. *See OddzOn*, 122 F.3d at 1405 (claim must be limited to the overall ornamental visual impression, rather than to the broader general design concept).

The claimed design does not cover the universe of designs that remotely resemble the basic design. The patent protects the ornamental features the patentee chooses and leaves other ornamental design features to the imagination of other designers. *See Sofpool LLC v. Kmart Corp.*, 2013 WL 2384331, *1, 5 (E.D. Ca., May 30, 2013) (the patent protects the shapes and proportions the patentee chooses, not every conceivable shape and proportion that could arise from its basic design.)

III. Discussion

The design claimed in the '922 patent and the accused design of Warsaw's 16mm NIM-Eclipse Direct Lateral Dilator are reproduced below.





Both dilators have a cylindrical main body, with a tapered section extending from the distal end of the cylindrical main body, and an electrode on the tapered section extensive with the distal edge of the tapered section. NuVasive argues that there is an overall appearance of sameness between the accused dilator and the patented design, or at least there is a factual dispute as to the sameness precluding the grant of summary judgment. NuVasive's assessment of sameness, however, as discussed below, is based on the general design concept and functionality of the devices. It disregards the actual overall visual differences in the ornamental aspects of the design and the accused dilator.

The patentee must show that the perceived similarity is based on the ornamental features of the design. "The patentee must establish that an ordinary person would be deceived by reason of the common features in the claimed and accused designs which are ornamental." *OddzOn*, 122 F.3d at 1405.

NuVasive provides the opinion of Dr. Hansen Yuan, a surgeon familiar with the selection and use of dilators in surgery, and identifies him as an ordinary observer. Dr. Yuan contends that the ordinary observer is a surgeon who would not notice the ornamental differences between the accused dilator and the patented design and would consider the devices interchangeable. [Doc. No. 246-5 (sealed), Infringement Report of Dr. Yuan, ¶34.]

In his report, Dr. Yuan describes how a surgeon selects a dilator during surgery. According to him, a representative of a medical device company, such as Warsaw or NuVasive, is present during surgery with kits containing devices such as the accused dilator

1 that may be needed during the surgical procedure. The representative would typically
2 know what devices are used in the procedure and would have the devices available and
3 ready at the start of surgery. When the surgeon requests a stimulated dilator, the medical
4 device representative provides the instrument from his or her company's kit. [Doc. No.
5 246-5, ¶¶31-32.]

6 In this context, Dr. Yuan's analysis then focuses on the functional similarities
7 between the accused dilator and the dilator design. He concludes that as long as the design
8 differences do not impact the functionality of the dilator, the surgeon simply would not be
9 looking for them and would not notice or appreciate them. [*Id.*, ¶34; Doc. No. 248, at 11.]
10 In his opinion, even fairly dramatic changes in the size, shape, or location of the electrode,
11 or the degree of the taper of the tip, are not meaningful as long as they do not impact
12 functionality. [*Id.*, at 6.]

13 It is NuVasive's contention that these features, the actual design choices that the
14 patent protects, such as the shape of the electrode, the precise location of the electrode, or
15 the degree of taper, are "minor differences" that do not defeat the substantial similarity
16 between the two dilators, because they ultimately do not impact the functionality of the
17 dilator. As long as the functionality of the two dilators is interchangeable, differences in
18 design are irrelevant and the structural overall visual impression is sufficiently similar
19 because one dilator could be used as well as the other. [Doc. No. 246-5, ¶40; Doc. No.
20 248, at 11.]

21 The Court finds that Dr. Yuan's infringement opinion that the accused dilator and
22 the design are functionally interchangeable does not assist in the analysis of the similarity
23 of the ornamental aspects of the accused dilator and the patented design. Dr. Yuan
24 concludes that he would not notice or care about the design differences, despite
25 acknowledging that there are visible differences, because he considers the patented design
26 and the accused dilator functionally interchangeable. It is however the very features that
27 he disregards as minor that the patent protects.
28

1 Dr. Yuan recognizes that the electrode on the accused dilator is “skinnier and longer
2 than the surface marking shown in the NuVasive design patent” and that it “extends slightly
3 above the shoulder of the taper, rather than terminating slightly below it,” but he concludes
4 that a typical surgeon would not notice or appreciate these variations.⁴ A typical surgeon,
5 he states, “might notice whether or not an electrode is present, and perhaps its general shape
6 (such as rectangular or triangular). But beyond that, variations in the dimensions of the
7 electrode are not something that a typical surgeon would notice or appreciate at the time of
8 purchase or use of the dilator (i.e., right before or during surgery.)” [*Id.*, ¶40.]

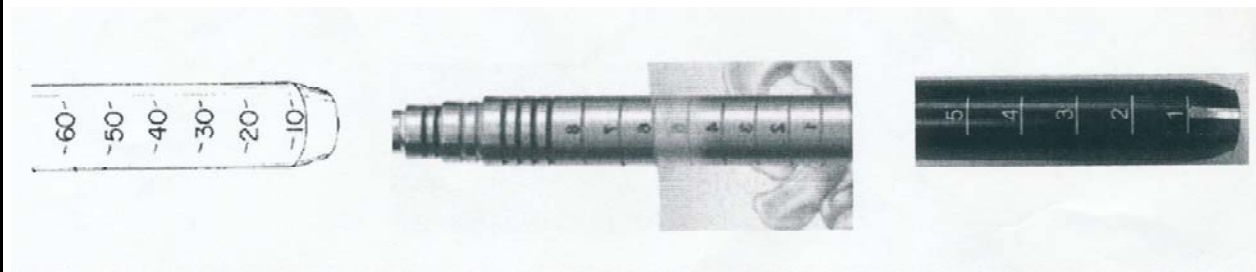
9 However, as the PTAB stated, the shape and orientation of the electrodes are the
10 design elements covered by the patent, not simply the presence or absence of an electrode
11 on the tapered section. [Doc. No. 174-6, at 8 (the surface indicia/electrode is not purely
12 functional as its function can be accomplished by different shapes and orientations).] A
13 design patent protects the ornamental features the patentee chooses, not every conceivable
14 shape of the basic design. *See Sofpool*, 2013 WL 2384331, *5. In this case, the designer
15 of the ‘922 patent selected the shape of a rectangle for the electrode that is oriented
16 extensive to the distal edge of the tapered section and terminates short of the cylindrical
17 main body. In contrast, the accused device utilizes a narrow strip with a curved end for the
18 shape of the electrode that is oriented extensive to the distal edge of the tapered section but
19 terminates past the tapered section on the cylindrical main body.

20 Dr. Yuan also recognizes that the accused dilator has numbered depth markings
21 along the main body of the dilator and that the claimed design has no such markings. He
22 discounts this difference on the basis that the depth markings on the accused dilator are
23 almost entirely functional, not ornamental, and therefore need not be considered. “Any
24 ornamental aspect of these particular markings is minimal, and thus of minor importance
25 in the ultimate infringement analysis.” [Doc. No. 246-5, ¶41.] He also asserts that the depth
26

27
28 ⁴ The electrode on the accused dilator is also not rectangular in shape, but has a curved fourth side. Dr. Yuan’s opinion does not address this.

1 markings on the accused dilator, which he describes as an intermediate dilator, are not
 2 generally used by a surgeon and would be ignored. He therefore simply disregards this
 3 plainly visible dissimilarity. [Id., ¶42.]

4 Although such markings have a functional purpose, they can also have an
 5 ornamental aspect. As Warsaw demonstrated in its reply brief, different fonts, sizes, styles,
 6 and locations can be selected by the designer of a dilator to implement the functional aspect
 7 of depth markings. [Doc. No. 251, at 16.]

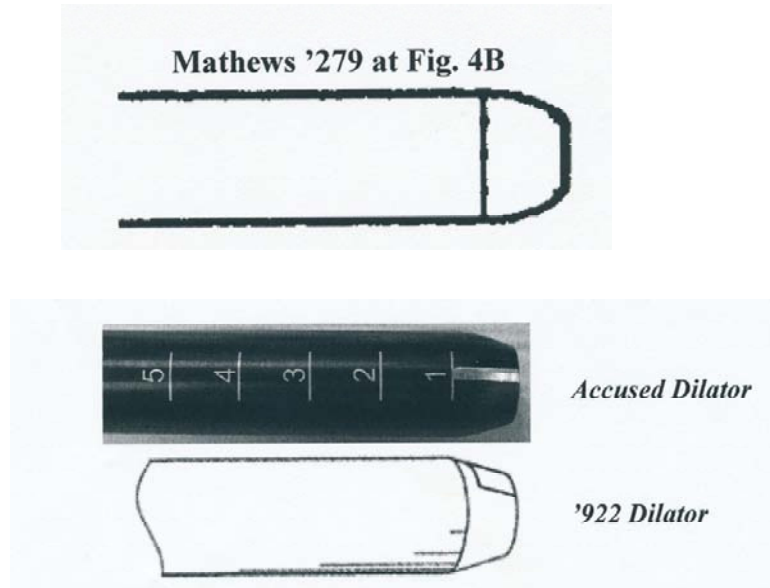


14 These choices are no less design choices than the selection of the size, shape and
 15 orientation of the electrode, or the shape and slope of the tapered tip of the dilator. Each
 16 aspect of the dilator has a functional purpose but can be expressed by a particular design
 17 selection. In the case of the patented design, the designer opted for no markings on the
 18 main body of the dilator. The difference between the accused device and the patented
 19 design is not an insubstantial difference between font selections. It is a visually distinct
 20 dissimilarity between the dilators, the accused dilator with markings on the main body and
 21 the design of the main cylinder chosen by the patentee, without markings or any
 22 measurement indicia.

23 Dr. Yuan makes no reference in his opinion to the visual difference between the
 24 shape of the tapered section of the accused dilator and the patented design. The PTAB, in
 25 its assessment of the patentability of the '922 design, specifically noted that there is a
 26 design aspect regarding the implementation of the functional purpose of the tapered end
 27 that makes the design patentable. To demonstrate that design aspect, the APJ described as
 28 noticeably different the more rounded shape of tapering used in a prior art dilator tube

1 compared to the frustoconical tapered section of the dilator claimed in the '922 patent.
2 [Doc. No. 174-6, at 7.]

3 The Court recognizes that the tapered portion of the accused dilator resembles that
4 prior art design described as noticeably different than the '922 design.



15 *Egyptian Goddess*, 543 F.3d at 681 (“An ordinary observer, comparing the claimed and
16 accused designs in light of the prior art, will attach importance to differences between the
17 claimed design and the prior art depending on the overall effect of those differences on the
18 design.”)

19 Observing the overall ornamental aspects of the '922 design patent in comparison to
20 the accused device, they are plainly dissimilar. NuVasive offered no evidence that an
21 ordinary observer aware of the prior art would find the overall ornamental aspects of the
22 design and the accused device to be substantially similar. *See Richardson*, 597 F.3d at
23 1295 (from the perspective of an ordinary observer familiar with the prior art, there must
24 be substantial similarity in the overall visual effect of the accused device and the patented
25 design).

26 Dr. Yuan’s opinion that the design dissimilarities are minor because they do not
27 impact the functionality of the dilator does not create a material dispute. His opinion as to
28

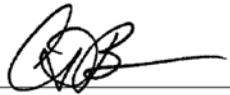
1 the similarity of the design and the accused device is not based on the protected ornamental
2 features, which he asserts he would not notice, but on the similarity of the broader general
3 design concept that he concludes makes the dilators functionally interchangeable.⁵
4 Functional interchangeability is not the proper test, and a jury cannot find infringement
5 based on Dr. Yuan's opinion of functional similarity. NuVasive has not met its burden to
6 demonstrate a substantial similarity of the protected ornamental features.

7 **IV. Conclusion**

8 The overall ornamental aspects of the 16mm NIM-Eclipse Direct Lateral Dilator are
9 not substantially similar to those of the '922 patent design. The Court finds that NuVasive
10 cannot establish by a preponderance of the evidence that an ordinary observer would be
11 deceived into thinking that the accused device is the same as the patented design. Warsaw's
12 motion for summary judgment of non-infringement is **GRANTED**.

13 **IT IS SO ORDERED.**

14 Dated: October 20, 2015

15 
16 _____
17 Hon. Cathy Ann Bencivengo
18 United States District Judge
19
20
21
22
23
24
25
26

27 ⁵ As part of its motion for summary judgment, Warsaw also moved to exclude Dr. Yuan's opinion as
28 legally erroneous. [Doc. No. 246, at 22-27.] The Court considered Dr. Yuan's opinion and found it did
not inform the analysis. Warsaw's request to exclude is deemed moot.